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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/636,104 | 08/10/2000 | Xiaobo Wang | 47184-20001.00 | 6349 |

25225 7590 12/23/2004
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EXAMINER

NOGUEROLA, ALEXANDER STEPHAN

| ART UNIT | PAPER NUMBER |
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1753

DATE MAILED: 12/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|------------------------------------|--|
| Office Action Summary | Application No. 09/636,104 | Applicant(s) WANG ET AL. | |
| | Examiner ALEX NOGUEROLA | Art Unit 1753 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 11-18, 20, 23-25, 28, 32-34, 36-38, 40, 41, 43-48 and 50-69 is/are pending in the application.
- 4a) Of the above claim(s) 53-67 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7, 8, 11-18, 20, 23-25, 28, 32, 33, 45-48, 50-52, 68, and 69 is/are rejected.
- 7) ☒ Claim(s) 6, 34, 36-38, 40, 41, 43 and 44 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 August 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Rejections pending since the Advisory Action of September 27, 2004

1. All previous rejections are withdrawn.

Claim Objections

2. Claim 1 is objected to because of the following informality: in line 3 -- a -- should be inserted between "onto" and "surface".

Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 1753

4. Claims 1-5, 7, 8, 11-18, 20, 23-25, 28, 32, 45, 48, 50, 51, and 68 are rejected under 35 U.S.C. 102(b) as being anticipated by Weetall et al. (US 5,620,857). See the abstract; Figure 1; col. 3:32-46; col. 3: 53-59; col. 4: 39-41; col. 5: 45-62; col. 6:15-23, col. 6:60-67 (competitive binding implies cleavable linkage), col. 7:63 – col. 8:3. Note that the structure comprising the cover slip (15) and well (17) at the top of Figure 1 can be construed as the chip of claim 1, the lens shown (but not labeled) in Figure 1 can be construed as the “structure that is built-in in said chip” of claim 1, and the laser of Figure 1 can be construed as the “signal source that is external to said chip.” Also, Weetall specifically mentions using a “chip” format. See col. 7:63 to 8:1.

For claim 14, note that as evidenced by the CAPLUS abstract of Drake et al., carbodiimide is cleavable (Weetall col. 5:45-52).

For claims 20 and 23-25 note that claim 1 does not necessarily require a dielectrophoresis force, an acoustic force, or an electrostatic force. These forces are only in the alternative, along with optical force, which Weetall discloses.

For claims 68, Applicants should note that paragraph (c)(i)-(viii) are only intended uses that do not further structurally define the claimed invention because claim 68 does not require a moiety. Also, how the moiety is to be manipulated does not imply means for carrying out such manipulation.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 33, 46, 47, 52, and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weetall et al. (US 5,620,857) ("Weetall").

Addressing claim 33, Weetall discloses a method as required by claim 1. See the rejection of claim 1 under 35 U.S.C. 102(b), above. Weetall does not mention “decoupling the moiety from the surface of the binding partner after the moiety is manipulated.” It would have been obvious to one with ordinary skill in the art at the time the invention was made to so decouple the moiety because then the binding partner could be reused for another sample containing the same or a different moiety. That the moiety can be decoupled from the binding partner is disclosed indirectly from at least one embodiment of Weetall, in which competitive binding is disclosed. See col. 6:60-67 and col. 5:55 – 6:12.

Addressing claims 46 and 47, Weetall does not mention the claimed ranges for coupled moiety. However, Weetall does disclose a very wide range for concentrations of coupled moiety (1.49×10^{-5} M to 1.49×10^{-15} M). See col. 5:45-52. Thus, barring evidence to the contrary, such as unexpected results, the extent to which moiety is coupled to the surface of the binding partner is a matter of optimizing the method for the detection limit and amount of moiety. See col. 6:15-28.

Addressing claim 52, Weetall discloses a method as required by claim 50. See the rejection of claim 50 under 35 U.S.C. 102(b), above. Although Weetall does state that several assays can be run on one sample, it is not mentioned whether they are run simultaneously or sequentially. It should be first noted that these options are exclusive; that the sample can only be run simultaneously or sequentially. In any event, whether to run to samples simultaneously or

Art Unit: 1753

sequentially, barring a contrary showing is arbitrary. To run the samples simultaneously can, for example, be accomplished by just duplicating parts; that is, making several wells and providing one or more lasers as shown in Figure 1 of Weetall.

Addressing claim 69, Weetall discloses a method as required by claim 68. See the rejection of claim 68 under 35 U.S.C. 102(b), above. Although Weetall does not mention providing instructions for coupling the moiety onto the surface of the binding partner and/or manipulate the moiety-binding partner complex on the chip, it would have been obvious to one with ordinary skill in the art at the time the invention was made to do so because then the operator of the kit will have to lose less time with trial and error experiments on how to use the kit.

Allowable Subject Matter

9. Claims 6, 34, 36-38, 40, 41, 43, and 44 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. The following is a statement of reasons for the indication of allowable subject matter:

a) Claim 6: Weetall only discloses organic molecules, biochemical molecules, and biological cells, cell components, and viruses as possible moieties. See col. 3:53-62;

Art Unit: 1753

b) Claims 34 and 36: in Weetall a complementary DNA strand is covalently coupled to a latex bead via carbodiimide. See col. 7:1-23;

c) Claim 37 requires the surface of a binding partner to be modified with a detergent. In Weetall the surface of the binding partner is modified with carbodiimide. See col. 5:44-52;

d) Claim 38 depends from allowable claim 37; and

4) Claims 40, 41, 43, and 44 require manipulation by one of dielectrophoresis force, a traveling-wave dielectrophoresis force, an acoustic force, or an electrostatic force. Weetall uses an optical radiation force. See the abstract.

Priority

11. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in China on August 08, 2000. It is noted, however, that applicant has not filed a certified copy of the Chinese application as required by 35 U.S.C. 119(b).

Art Unit: 1753

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Alex Nogueraola
Primary Examiner
AU 1753
December 21, 2004